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Adverse Drug Reaction & Reporting in A Tertiary Care Teaching Hospital in Bangladesh

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ABSTRACT: ***Background:*** An adverse drug reaction (ADR) is a common clinical problem while treating a patient. Adverse drug reaction (ADR) is the undesirable effect of medicine that occurs beyond its known therapeutic effects. This study aimed to obtain information about the detection of ADR and the status of ADR reporting in a tertiary care teaching hospital. ***Methods:*** This observational study was conducted at the Department of Pharmacology, Dhaka Medical College, Bangladesh, from July 2019 to June 2020. A total of 600 patients were selected by purposive sampling technique as per inclusion and exclusion criteria. Collected data were analyzed using descriptive statistics. Continuous data were expressed as mean ± SD (standard deviation) and the nominal data were expressed as percentages. Analysis of data was carried out by using a statistical package for social science (SPSS) 22.0 for Windows. ***Result:*** Among the three departments, the highest number of patients with ADR was detected in the pediatric department (56.3%), followed by the dermatology department (31.3%), and the lowest (12.5%) in the medicine department. Among 16 ADRs (who developed ADRs) only 1 (6.30%) patient was reported to the relevant authority which was the pediatric department and 15 patients with ADRs were underreported. ***Conclusion:*** Most of the detected ADRs were underreported. In Bangladesh, the importance of ADR is still underestimated with inadequate reporting, inappropriate data collection, storage, and analysis. Thus, adverse drug reaction reporting systems need to be robust to be able to detect new drug alerts and improve pharmacovigilance.

Keywords: Adverse Drug Reaction, Reporting, Pharmacovigilance, Dermatology, Medicine.

Article at a glance:

Study Purpose*: The purpose of this study is to evaluate the incidence, patterns, and reporting practices of adverse drug reactions (ADRs) in a tertiary care teaching hospital in Bangladesh.*

Key findings: *A significant number of ADR cases were observed, affecting patients across various departments, particularly in internal medicine, cardiology, and oncology.*

Newer findings: *Recent studies emphasize the effectiveness of digital and mobile-based ADR reporting systems in improving reporting rates.*

Abbreviations: *ADRAC: Adverse Drug Reaction Advisory Committee.*

INRODUCTION

ADR is defined as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modifications of physiological function".[1] ADRs are associated with significant morbidity and mortality.[2] A 15-years boy died in 2005 following an intake of levofloxacin which is prescribed to treat bacterial infections. He had suffered severe forms of adverse drug reactions, but it was too late by the time it was diagnosed. This was the first case of adverse drug reaction reported in the country. The second similar fatal case was reported three years later of a 40-year-old female. These two cases might be the extreme outcome of medical drugs, but to experience side effects that are unknown to a

drug even after it gets licensed and authorized is not unexpected – not to the healthcare providers and manufacturers. That is why reporting adverse drug reactions is crucial to ensuring medicine safety. Adverse drug reaction reporting helps the drug monitoring system detect the unwanted effects of those drugs, that are already in the market. They affect both children and adults with varying magnitudes, causing both morbidity and mortality.[3] The information collected during the pre-marketing phase is incomplete about adverse drug reactions and this is mainly because patients used in clinical trials are limited in numbers and are not representative to the public at large. In addition, the conditions of use of medicines differ from those in clinical practice and the duration is limited. Information about rare but serious adverse reactions, chronic toxicity, and use in special groups (Such as children, the elderly, or pregnant women) or drug interactions is often incomplete. Therefore, post-marketing surveillance is important to permit the detection of less common but sometimes very serious ADRs.

Therefore, health professionals worldwide should report on ADRs as they can save the lives of their patients and others.[4] Different studies have documented that, new adverse reactions are discovered more efficiently from spontaneous reporting than from other methods. Including large post-marketing studies.[5] However, the incidence of spontaneous reporting is on the lower side due to the lack of awareness of the need for reporting.[6] Drugs are double-edged weapons, they are used in the treatment of patients but in return can harm as well. The safety of drug prescribing has become a need-of-the-hour topic in medicine. Safety monitoring of patients via pharmacovigilance tools has become an integral part of pharmacotherapy. At a global level as well drug toxicity is playing a major limitation in providing good health care to patients by affecting health and economic burden.[7] The national guideline on the pharmacovigilance system in Bangladesh (NGPSB) was established in 2017. Pharmacovigilance aims at making the best use of medicines with the help of high-quality data gathered through a reporting system. Good pharmacovigilance helps in the minimization or prevention of ADRs through early detection and effective communication, which ultimately help each patient to receive optimum therapy. It can generate evidence that will inspire public confidence and trust in drugs.[8] In Bangladesh, physicians, other health professionals, and patients/ consumers are not adequately aware of ADR, which is an issue of great concern. Preventing ADRs' active involvement of physicians in the spontaneous reporting of ADRs is essential for the effective implementation of the national pharmacovigilance program.[9] Hence, the present study was designed to obtain information about the detection of ADR and the status of ADR reporting in a tertiary care teaching hospital.

OBJECTIVES

General Objective

To obtain information about the detection of ADR and the status of ADR reporting in a tertiary care teaching hospital.

Specific Objectives

To know the age and gender distribution among the respondents

To see the educational status of the participants.

To assess the distribution of the study patients by department.

To recognize the responsible drugs identified for ADR.

To analyze the severity of ADR among the patients

METHODS

This observational study was conducted at the Department of Pharmacology, Dhaka Medical College, Bangladesh, from July 2019 to June 2020. All the patients admitted to the medicine, dermatology, and pediatric ward of Dhaka Medical College Hospital fulfilling the inclusion and exclusion criteria were considered as the study population. A total of 600 patients were selected by purposive sampling technique.

Inclusion Criteria

Patients who are admitted to medicine, dermatology, and pediatric wards of Dhaka Medical College Hospital.

Patients who were diagnosed as ADR on admission or later after admission.

Patients of both genders and ages < 80 years.

Patients who were willing to give consent.

Exclusion Criteria

Patients who were not willing to give consent.

Patients who developed an ADR due to poisoning of drugs (Accidental or intentional), blood or blood products, and vaccines.

ADRs due to alternate systems of medicines like homeopathy, Ayurvedic, Unani, etc. were excluded from the study.

Data Collection

Data were collected in a specially designed data collection form. A prescription audit was done to find out the patient's record which includes confirmed clinical diagnosis, patient profile, clinical history, medication charts, laboratory data, and other relevant data were reviewed and necessary data were collected according to the objectives of the study. Filling out the ADR form and sending it to the ADRAC (Adverse Drug Reaction Advisory Committee) of the Directorate General of Drug Administration through appropriate authority was regarded as ADR reporting. Follow-up was done with the authority (DGDA) after three months of data collection whether any case was reported or not. Based on objectives, extent of ADR reporting, types of ADR occurring, severity grading of ADRs was evaluated considering the National Guideline on the pharmacovigilance system in Bangladesh (2017) recommendations. Collected data were analyzed using descriptive statistics. Continuous data were expressed as mean ± SD (standard deviation) and the nominal data were expressed as percentages. Analysis of data was carried out by using a statistical package for social science (SPSS) 22.0 for Windows. Ethical clearance was taken from the Ethical Review Committee (ERC) of the same institute. Informed written consent was obtained from the participants.

RESULTS

Table 1: Distribution of Respondents by Their Age in Years (N=600)

Age group (years)	n	%	Mean± SD (range)
<10	215	35.8	
11-20	30	5.0	
21-30	65	10.8	
31-40	96	16.0	27.8±21.4
41-50	88	14.7	(0.60 – 80) years
51-60	80	13.3	
61-70	18	3.0	
71-80	8	1.3	
Total	600	100.0	

In this series, the highest number of the respondents (215, 35.8%) were in the age group <10 years, followed by the age group 31-40 years (96, 16.0%), and the lowest number of respondents (8, 1.3%) were in the age group 71-80 years. The mean age of our patients was 27.8 ± 21.4 years. [Table 1]

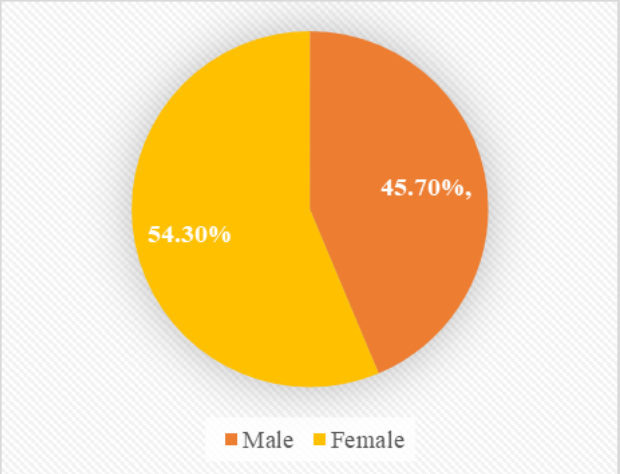

Figure 1: Gender Distribution of Respondents (N=600)

It was observed that male to female ratio was 1:1.2. Males were 274 (45.7%) and females were 326 (54.3%) in number. [Figure 1]

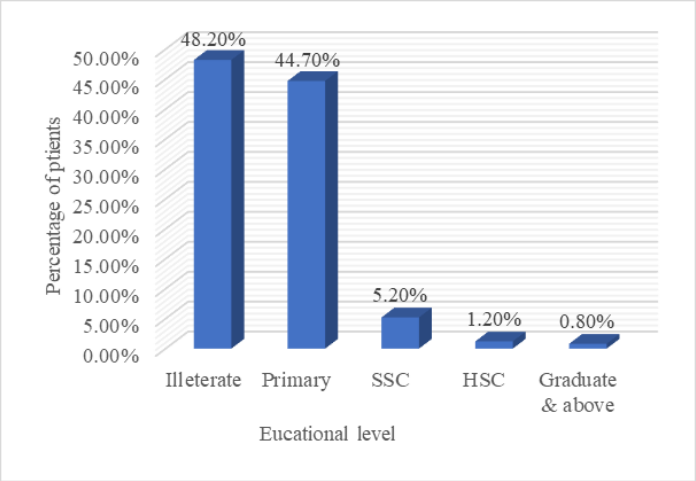

Figure 2: Educational Status of The Participants (N=600)

SSC: Secondary School Certificate; HSC: Higher Secondary Certificate.

Among 600 patients, 289 (48.2%) patients were illiterate, 268(44.7%) patients were educated by primary education, 31(5.2%) patients were SSC, 7 (1.2%) patients were HSC and 5 (0.8%) patients were graduate and above. [Figure 2]

Table 2: Distribution of the study patients by department (N=600)

Department	n	%
Pediatrics	202	33.7
Medicine	197	32.8
Skin/ Dermatology	201	33.5
Total	600	100.0

In this study, 202 (33.70%) patients were from the pediatrics department, 201 (33.5%) patients were from the dermatology department and 197 (32.8%) patients were from the medicine department. [Table 2]

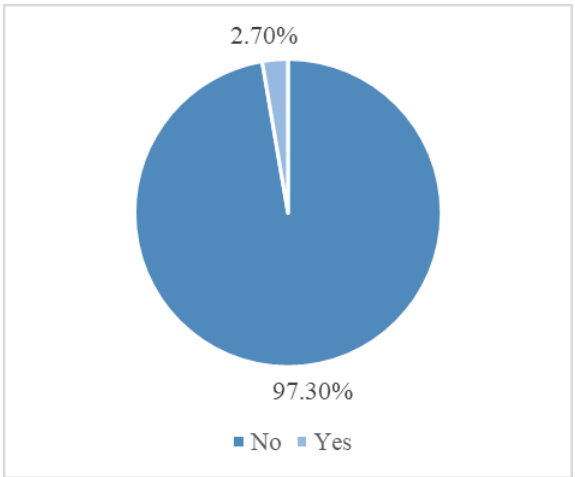

Figure 3: Distribution of The Study Patients by ADR Detection (N=600)

Out of 600 patients, adverse drug reaction was detected in 16 (2.70%) patients, and 584 (97.30%) patients did not develop any adverse drug reaction. [Figure 3]

Table 3: Distribution of The Study Patients by Department Basis ADR Detection (N=600)

Department	ADR		Total	p-value
	Yes (n=16) No. (%)	No (n=584) No. (%)	(n=600) No. (%)	
Pediatrics	9(56.3%)	193(33.0%)	202(33.7%)	
Dermatology/skin	5(31.3%)	196(33.6%)	201(33.5%)	0.101[ns]
Medicine	2(12.5%)	195(33.4%)	197(32.8%)	
Total	16(100%)	584(100%)	600(100%)	

A chi-square test was done, ns= not significant

There was no significant difference (P<0.05) in the detection of ADRs in different departments of Dhaka Medical College Hospital. Among the three departments, the highest number of patients with ADR was detected in the pediatrics department (56.3%), followed by the dermatology department (31.3%), and were lowest (12.5%) in the medicine department. [Table 3]

Table 4: Distribution of Responsible Drugs Identified for ADR (n=16)

Offending drugs	n (%)	ADR type	n
Cotrimoxazole	4(25.0%)	Toxic epidermal necrolysis (TEN)	1
		Steven Johnson syndrome	2
		Drug allergy/hypersensitivity	1
Vancomycin	3(18.8%)	Bullous drug reaction	1
		Drug-induced rash	1
		Drug allergy/hypersensitivity	1
Ciprofloxacin	2(12.5%)	Bullous drug reaction	1
		Drug allergy/hypersensitivity	1
Diclofenac	2(12.5%)	Drug induced vasculitis	1
		Drug-induced rash	1
Na valproate	2(12.5%)	Gum bleeding with diarrhea	1
		Toxic epidermal necrolysis (TEN)	1
Ceftriaxone	1(6.3%)	Steven Johnson syndrome	1
Paracetamol	1(6.3%)	Drug-induced rash	1
Amikacin	1(6.3%)	Steven Johnson syndrome	1
Total	16(100.0%)		

Among 16 patients, 4 (25%) showed ADR due to cotrimoxazole, 3(18.8%) vancomycin, 2 (12.5%) ciprofloxacin, 2 (12.5%) Diclofenac, 2 (12.5%) Na-valproate, 1 (6.3%) ceftriaxone, 1 (6.3%) paracetamol and 1 (6.3%) amikacin. [Table 4]

Table 5: Distribution of ADR Patients According to Severity (n=16)

Severity	n	%
Mild	4	25.0
Moderate	9	56.3
Severe	3	18.7
Total	16	100.0

Among 16 ADR cases 4 (25.0%) ADR cases were mild, 9 (56.3%) were moderate and 3 (18.7%) were severe. [Table 5]

It was found that 81.3% of ADR cases were prescribed with polypharmacy and 18.7% without polypharmacy. [Figure 3]

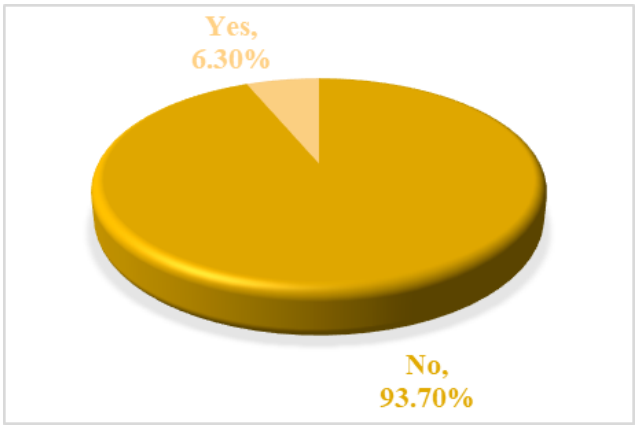

Figure 3: Distribution of ADR Patients According to Reporting Status (n=16)

Among 16 ADRs (who developed ADRs) only 1 (6.30%) patient was reported to the relevant authority and 15 patients with ADRs were underreported. [Figure 3]

Table 6: Department Basis Distribution of ADR Reporting Status (N=16)

Department	n	%
Medicine	0	0.0
Skin/ Dermatology	0	0.0
Pediatric	1	6.3
Underreporting	15	93.7
Total	16	100.0

It was observed that among 16 ADRs only 1 ADR was reported by the pediatric department, whereas the medicine and skin department did not report any ADR. [Table 6]

DISCUSSION

This study showed prominent age group was 0-10 years (35.8%). The generated results exhibited similarity with the study done by Chowdhury *et al.*, in which the majority (40%) of patients were in the age group 0-15 years.[10] This reflects that adverse drug reaction is more common in the pediatric age group. Another study done by Vijayakumar *et al.*, justified that geriatrics (53%) were a more vulnerable population.[11] In this study, the demographic profile showed that female (54.3%) patients were higher than male (45.7%). Similar findings were found in the study done by James and Rani *et al.*, which showed females 60% and males 40%.[12] Gender-related differences that are relevant for the pharmacokinetic and pharmacodynamic behavior of drugs include differences in physiology, genetic expression, immunological process, and type of various hormones involved in the pathogenesis of adverse drug reactions.[13] In this study detection of ADR was 2.7%. Similar findings were found in the study done by Gor and Desai *et al.*, in which the detection of ADR was 3%.[14] Similar studies were done in Egypt and India where ADRs were 9.52% and 0.01% respectively.[15, 16] According to Mudigubba *et al.*, the adverse drug reaction was 13% which was higher than in another study.[17] The difference in ADRs among the studies is due to the variation in the selected settings, data collection methods, and methodologies used. Antimicrobial agents (68.8%) were the most common suspected drugs causing ADRs in our study. The second most causative agent was NSAIDs (18.7%). A similar finding was found in to study conducted by Begum, *et al.*, where antibiotics were the most common cause of ADRs (42.9%) and 33.3% were due to NSAIDs.[18] Adverse drug reactions impose a significant burden on hospitals by prolonging

patients' stay and increasing admission rates. In the Current study, the department basis detection of ADR was 56.3% in pediatrics, 31.3% in dermatology, and 12.5% in the medicine department. Which is not too far from the study done by Begum, *et al.*[18] Another study done by Parvin *et al.,* where found ADR in the dermatology department was 9%. This finding did not match with our study.[19]

According to Gor and Desai *et a*l, who revealed ADR in the medicine department was 3% which is not comparable to the present study.[14] In this study severity assessment by ADR severity grading scale showed 56.3% ADR as moderate and 25% as mild which is a similar finding to the study done by Begum *et al.,* where 31.6% mild and 42.1% were moderate eases.[18] The result was not in coherence with the study conducted by Misra, *et al.,* where 86.7% ADRs were mild and 13.3% moderate.[16] Reporting ADR is useful for identifying and reducing preventable reactions. The detected ADRs reported in our study was 6.3%. These results were near to the findings of Arulmani *et al.,* in which 9.8% ADR was reported.[20] The lower number of adverse drug reaction reports could be due to many factors such as lack of time, and lack of awareness about reporting. In this current study, the department reporting maximum ADR is pediatric (6.3%). A similar finding was found in to study done by Impiceiatore *et al.,* where the pediatric department reported ADR was in the range of 4.37 to 16.78% average was 9.53%.[21] Another study done by Misra, *et al.,* which shown the department reporting the maximum ADR is general medicine (41.9%) which is not comparable to the present study.[16] The reason may be due to the detection of ADR was higher in the pediatric department.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community. Moreover, outdoor patients of ADR were not included in this study.

CONCLUSION

This study concludes that most of the detected ADRs were underreported. In Bangladesh importance of ADR is still underestimated with inadequate reporting, inappropriate data collection, storage, and analysis. Thus, adverse drug reaction reporting systems need to be robust to be able to detect new drug alerts and improve pharmacovigilance.

Recommendation

This study warrants further research for the development of possible intervention strategies to reduce the burden of adverse drug reactions. To improve detection and reporting, scientific understanding of ADR as a 'Drug-induced disease' requires further scientific research. Moreover, further studies should be conducted in this context involving a large sample size and multiple centers with long duration.

Authors' Contributions

SA, AKD, MSH: Concept and design, data acquisition, interpretation and drafting. MKN, TA and SN: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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Ethical approval: The study was approved by the Institutional Ethics Committee.

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